Division of Medical Assistance	**Clinical Coverage Policy No. 11A-11**
High Dose Chemotherapy, Bone Marrow or Peripheral Stem Cell Transplant for Non-Hodgkins Lymphoma	**Original Effective Date: January 1, 1994** **Revised Date: December 1, 2005**

Introduction

Specialized services for blood and marrow transplantation include both autologous and allogeneic stem cell transplants. The principle underlying stem cell transplantation is the transfer of hematopoietic stem cells after the administration of high dose chemotherapy, with or without radiotherapy. The source of hematopoietic stem cells can be either bone marrow (bone marrow transplants, BMTs) or the peripheral blood (peripheral blood stem cell transplants, PBSCTs). The fetal blood harvested from the placenta and umbilical cord is also a stem cell source (cord blood transplants).

Autologous stem cell support/ transplantation (previously referred to as an autologous bone marrow transplant) involves re-infusing intravenously a portion of the patient's own stem cells to rescue the patient and re-establish his/her bone marrow which has been eradicated by high dose chemotherapy/radiotherapy used to destroy malignant cells. Autologous stem cells can be harvested from bone marrow or from circulating blood through the process of pheresis. Tandem transplantation is defined as two or more planned courses of high dose chemotherapy with stem cell support.

Allogeneic stem cell transplantation involves the administration of blood or marrow stem cells from either a family member (usually an HLA matched sibling but on occasions a haploidentical relative) or a matched unrelated donor following administration of chemo/radiotherapy. The genetic disparity between donor and recipient means that allogeneic transplantation is associated with a number of life-threatening complications including graft-versus-host disease, graft rejection and delayed immune reconstitution. Immunologic compatibility between donor and patient is a critical factor for achieving a good outcome. Cord blood donors do not have to be matched as closely as bone marrow or peripheral blood progenitor cell donors.

The following policy contains the minimal criteria for stem cell transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Prior Approval staff.

1.0 Definition of the Procedure

High dose chemotherapy involves the administration of cytotoxic agents using doses several times greater than the standard therapeutic dose followed by infusion of bone marrow or stem cells in order to repopulate the bone marrow.

Lymphoma is a general term for cancers that develop in the lymphatic system. Hodgkin's disease is one type of lymphoma and all others are grouped together and called Non-Hodgkin's lymphoma (NHL). NHL's are neoplasms arising from lymphocytes arrested at various stages of maturation. NHL can be categorized according to their histologic type, their grade, stage, on the basis of immunophentyping, or a combination of the above. The most commonly used classification systems are the International Working Formulation Classification, Modified Ann Arbor Staging System for Lymphoma's or the Ann Arbor Staging System for Lymphoma proposed by the National Cancer Institute.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

The N.C. Medicaid program covers this procedure in patients who meet the following conditions:

3.1 **Autologous** transplant: high dose chemotherapy, autologous bone marrow or peripheral stem cell support for the treatment of Stage 111-A, 111-B, 1V-A or B at the time of relapse, when **all** of the following criteria are met:

1. Histology type: intermediate-grade 1 (follicular large cell, diffuse, small cleaved cell, diffuse mixed and large, diffuse large cell) or High grade-1 (large cell, immunoblastic, lymphoblastic, small, non cleaved cell, Burkitts)
2. Evidence of chemotherapy responsive
3. Less than 65 years old
4. No evidence of serious organ dysfunction:
   a. creatinine clearance > 40ml/min or serum below 2mg/ml
   b. no history of severe chronic liver disease (total bilirubin $\leq$ 1.5 mg/dl)
   c. LVEF > than or equal to 45%
   d. PFT (FVC, FEV1) > or equal to 60% of predicted

3.2 **Allogeneic** bone marrow or peripheral stem cell transplant for treatment of relapsed, or primary refractory NHL (low grade, intermediate-grade, and high grade) when **all** the criteria are met:

1. Less than 55 years old
2. HLA matched donor
3. No serious organ dysfunction:
   a. LVEF greater or equal to 45%
   b. PFT (FVC, FEV1) greater or equal to 50%

3.3 **Non-myeloablative** allogeneic bone marrow transplant (mini-transplant, reduced intensity conditioning transplant) **is covered** for relapsed or primary refractory NHL (low, intermediate and high grade) when eligible for conventional allografting.

3.4 **Individual Evaluation**
Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

4.0 When the Procedure is Not Covered

N.C. Medicaid program does not cover high dose chemotherapy bone marrow, or peripheral stem cell transplant for non-hodgkins lymphoma for the following:

4.1 **Autologous** bone marrow or peripheral stem cell transplant is not covered in the following situations if **any** of the following conditions are present:

1. Low grade histology.
2. Chemotherapy resistant disease, or resistant relapse.
3. Age 65 years or older.
4. Evidence of serious organ dysfunction.
5. Co-morbid diseases, i.e., poorly controlled diabetes mellitus, uncontrolled hypertension.
6. As initial therapy.
7. In relapse with transformation to higher grade histology.
8. Tandem transplant.
9. Mantle cell lymphoma.
10. History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

    Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
11. Psychosocial history that would limit the ability to comply with medical care pre and post transplant.
12. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.2 **Allogeneic** bone marrow or peripheral stem cell transplant is not covered in the following situations if **any** of the following conditions are present:

1. Age greater than 55 years old.
2. Evidence of serious organ dysfunction.
3. Co-morbid diseases i.e., uncontrolled hypertension, poorly controlled diabetes mellitus.
4. As initial therapy.

5. In relapse with transformation to higher grade histology.
6. Mantle cell lymphoma.
7. In relapse after HDC and autologous stem cell support.
8. History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

   Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
9. Psychosocial history that would limit the ability to comply with medical care pre and post transplant.
10. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.3 Individual Evaluation

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

If prior approval has been given for stem cell transplants, donor expenses (**procuring, harvesting, short-term storing and all associated laboratory costs**) are covered.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Providers bill professional services on the CMS-1500 claim form.
2. Donor expenses are billed on the recipient claim.
3. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered include:

38204	38205	38206	38207	38208	38209	38230	38240
38241	38242	86812	86813	86816	86817	86821	86822
96400	96405	96406	96408	96410	96412	96414	96420
96422	96423	96425	96440	96445	96450	96545	G0267
S2150	J9000 through J9999						

D. Providers must bill their usual and customary charges.